

K 122914

510(k) Summary of Safety and Effectiveness

Date Prepared: September 21, 2012

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establish Registration Number: 2184009

JAN 09 2013

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Trade Name: Affinity Fusion® Cardiotomy/Venous Reservoir with Balance®
Biosurface

Common Name: Cardiotomy Venous Reservoir

Classification Name: Cardiopulmonary bypass blood reservoir

Classification: Class II, 21 870.4400

Product Code: DTN

Name of Predicate Device: Affinity® NT Cardiotomy/Venous Reservoir with Filter Model 540
(K936003)

Device Description:

The Affinity Fusion® Cardiotomy/Venous Reservoir (CVR) with Balance® Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement. The inside of the jar is coated with Balance Biosurface to reduce platelet activation and adhesion and preserve platelet function. This product is single-use, nontoxic, nonpyrogenic, supplied STERILE in individual packaging. The Affinity Fusion Cardiotomy/Venous Reservoir is sterilized by ethylene oxide.

Intended Use:

The Affinity Fusion Cardiectomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiectomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

The Affinity Fusion Cardiectomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

Contraindications:

Do not use this device for any purpose other than indicated.

Do not use if air leaks are observed during priming and/or operation; this may result in air embolism to the patient and/or fluid loss.

The Affinity Fusion Cardiectomy/Venous Reservoir is contraindicated for use in postoperative chest drainage and autotransfusion procedures when:

- There is an air leak in the lung or gross perforations to the chest wall exist.
- Pericardial, mediastinal, pulmonary or systemic infection or malignancy is present.
- Gross contamination or a lymphatic failure is present or suspected.
- Suctioned blood is obtained from a site where a topical hemostatic agent has been used.
- The chest is open and vacuum is applied.
- Protamine has been administered prior to the reservoir being removed from the bypass circuit.
- The patient is returned to surgery for any reason.
- Vented chest tubes not incorporating vent flow regulation, such as a stopcock, are used.

Caution: An assessment should be made of the quality and suitability of the blood that has been collected before re-infusion begins.

Comparison to Predicate Devices:

A comparison of Affinity Fusion® Cardiectomy/Venous Reservoir with Balance® Biosurface to the predicate device indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Similar materials with the exception of the housing material of the device. The Affinity Fusion CVR housing is made of a Bisphenol A-free (BPA-free) copolyester material, which differs from the polycarbonate material used in the predicate device.

- Same shelf life

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device.

Clinical testing was not required to establish substantial equivalence with the predicate devices.

The following performance tests were conducted:

- Blood Damage
- Pressure Integrity
- Pressure Drop
- Leak Testing
- Defoaming
- Cardiotomy Filtration Efficiency
- Burst Pressure
- Coating Integrity
- Temperature Probe Accuracy
- Positive and negative pressure check valve function
- Minimum operating level
- Level sensor pull-off force
- Dynamic holdup
- Reliable fluid delivery
- Venous inlet prime
- Cap particulate shedding
- Device Particulate Shedding

Conclusion:

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface is substantially equivalent to the legally marketed predicate device, the Affinity® NT Cardiotomy/Venous Reservoir with Filter Model 540 (K936003).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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Medtronic CardioVascular
c/o Julia A. Nelson, MS, RAC
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Mounds View, MN 55112

Re: K122914

Trade Name: Affinity Fusion Cardiectomy/Venous Reservoir with Balance Biosurface
Model BB841

Regulation Number: 21 CFR 870.4400

Regulation Name: Cardiopulmonary Bypass Blood Reservoir

Regulatory Class: Class II (two)

Product Code: DTN

Dated: January 2, 2013

Received: January 3, 2013

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122914

Device Name:

Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface

Indications for Use:

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122914